PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
CMC-151WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/ 11620	28/04/2000	30/04/1999
Applicant		
CHILDREN'S HOSPITAL MEDICAL CENTER et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[ ] the text is approved as submitted by the applicant.

[X] the text has been established by this Authority to read as follows:

HEMOFILTRATION SYSTEM

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 3

[X] as suggested by the applicant.

[ ] None of the figures.

[ ] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/11620

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9306875 A	15-04-1993	US 5211849 A	18-05-1993
		AT 127352 T	15-09-1995
		AU 2862092 A	03-05-1993
		CA 2119375 A	15-04-1993
		DE 69204683 D	12-10-1995
		DE 69204683 T	25-04-1996
		EP 0607301 A	27-07-1994
		JP 7500036 T	05-01-1995
		US 5344568 A	06-09-1994
US 5503624 A	02-04-1996	AT 181844 T	15-07-1999
		DE 59408473 D	12-08-1999
		EP 0661065 A	05-07-1995
		ES 2133472 T	16-09-1999
		JP 7255842 A	09-10-1995
EP 0300201 A	25-01-1989	DE 3720665 A	05-01-1989
		JP 1097471 A	14-04-1989
		US 4923598 A	08-05-1990
EP 0611228 A	17-08-1994	US 5910252 A	08-06-1999
		AT 178496 T	15-04-1999
		CA 2115414 A	13-08-1994
		DE 69417608 D	12-05-1999
		DE 69417608 T	30-09-1999
		EP 0829265 A	18-03-1998
		ES 2131178 T	16-07-1999
		GR 3030578 T	29-10-1999
		JP 6315530 A	15-11-1994
		US 5679245 A	21-10-1997
		US 5776345 A	07-07-1998
		US 5762805 A	09-06-1998
WO 9850091 A	12-11-1998	AU 6849998 A	27-11-1998
		EP 0980275 A	23-02-2000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
CMC-151WO		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/11620	28/04/2000	30/04/1999

International Patent Classification (IPC) or national classification and IPC
A61M1/16

Applicant
CHILDREN'S HOSPITAL MEDICAL CENTER et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 15 sheets.

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
VI	☐	Certain documents cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16/11/2000	18. 07. 01

Name and mailing address of the international preliminary examining authority:

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/11620

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

2-50	as originally filed			
1,51-55	as received on	24/04/2001	with letter of	23/04/2001

Claims, No.:

1-18	as received on	24/04/2001	with letter of	23/04/2001

Drawings, sheets:

1/12-12/12	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 15,16,17,18.

because:

   ☒ the said international application, or the said claims Nos. 15,16,17,18 relate to the following subject matter which does not require an international preliminary examination (*specify*):
   see separate sheet

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-14
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Ad section III:

The method of controlling a pump according to the independent claims 15 and 16 necessarily includes to be carried out online, i.e. on the patient whereby better treatment conditions for the respective patient can be achieved, thus enabling for example more effective dialysis treatment. Therefore, said methods define inherently one part of a medical treatment process which cannot thought being separated from controlling said pump.

The independent claims 17 and 18 are directed to a treatment of the human or animal body practised on the body wherein blood is pumped from a patient and back to the same patient to enable a therapeutic effect on said patient. The Preliminary Examination Authority is not required to carry out an International Preliminary Examination for said claims with respect to Rule 67.1 iv PCT.

Ad section V:

Reference is made to the following documents:

D1: WO,A,93/06875
D2: ASAIO Journal 40 (1994), M686-M690

1) Independent claims 1, 8, 12 and 14

The most pertinent documents of the prior art are considered to be represented by D1 and D2. D1 discloses a conventional control system according to the features of the preamble of claims 1 and 8, wherein a programmable controller 12 connected to various components of the hemofiltration system is used to adjust the hemofiltration rate to the desired level by continuous or periodic interrogation of some parameters and by adjusting the corresponding pumping rates. D2 describes use of a fuzzy logic method to mathematically translate empirical measures to correct UF rates and sodium dialysate concentration when patient parameters such as blood volume and blood pressure are not within certain limits during

hemodialysis. D2 nor discloses the specific structure of the supervisory controller and the patient monitor as defined in the characterizing part of claim 1 nor the adaptive controller as defined in claim 8. Thus, claims 1 and 8 appear to meet the requirements of Art. 33(2) to (4) PCT.

Since the independent claims 12 and 14 incorporate the controller of claims 1 and 8, respectively, these claims also meet the requirements set out in Art. 33(2) to (4) PCT.

2) Dependent claims 2 to 7, 9 to 11 and 13

The dependent claims 2 to 7, 9 to 11 and 13 concern specific embodiments of the inventive concept of the independent claims to which they are referred and meet therefore also the requirements of Art. 33(2) to (4) PCT.

Ad section VII:

1) The unit of pressure employed on pages 51 to 54 is not additionally expressed in terms of the unit stipulated by Rule 10.1/(a)/and/(b) PCT.

2) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

Ad section VIII:

1) The wording of independent claim 1 concerning a supervisory rule is unclear making the claim as such unclear within the meaning of Art. 6 PCT since said rule is due its definition "predetermined" very vague. This objection also applies to the independent claim 8 with respect to the wordings "adaptive law" and "control law" which are completely undefined making said claim unclear under Art. 6 PCT.

2) Independent claim 14 is unclear (Art. 6 PCT) since **th** first reservoir mentioned in line 4 has no antecedent in said claim.

HEMOFILTRATION SYSTEM

Related Applications

This application is a continuation-in-part of patent application Serial No. 08/814,160, filed March 10, 1997, which is a continuation of patent application Serial No. 08/478,942, filed June 7, 1995, now abandoned, which is a continuation-in-part application of U.S. patent application Serial No. 08/299,899, filed September 1, 1994, which is a continuation of patent application Serial No. 08/062,928, filed May 17, 1993, now U.S. Patent No. 5,344,568 which issued September 6, 1994, which is a continuation of patent application Serial No. 07/775,183, filed October 11, 1991, now U.S. Patent No. 5,211,849 which issued May 18, 1993, and also claims the filing benefit of U.S. Provisional Application No. 60/131,955, filed April 30, 1999, each disclosure of which is hereby expressly incorporated by reference herein in its entirety.

Field of the Invention

The present invention is directed to a system and method of blood filtration, and more particularly supervisory control systems and methods and an

Table 3

Pump	Maximum Tracking Error	Maximum Prediction Error	Minimum No. of Samples for Validating An Incongruent Measurement of Flow
Blood	20 ml/min	20 ml/min	5
Drain	3 gr	3 gr	5
Replacement 1	3 gr	3 gr	5
Replacement 2	3 gr	3 gr	5

A brief disturbance of a large magnitude is introduced at a n=10 (by placing a large weight on the scale and removing it), and the supervisory controller does not react. At n=60, a similar, smaller disturbance is introduced for a brief period, and again, the supervisory controller does not respond. At n=90, a similar small disturbance is introduced, but for a prolonged period. This simulates a leak in the tubing, and is a much smaller disturbance than is generally encountered when leaks occur during actual ultrafiltration procedures. The controller detects the incongruent weight change and decides, in this case, to discontinue ultrafiltration.

Example 4

Figs. 10A, 10B, and 10C show simulated patient data and the desired drain rate for a simulation of ultrafiltration performed on a neonate. The patient heart rate and blood pressure are generated with computer software. The blood flow rate is set to 40 ml/min, and the replacement rates are both set to 100 ml/min. The thresholds for the heart rate are chosen as 90 bpm and 105 bpm, and the thresholds for the blood pressure are chosen as 70 mmHg and 95 mmHg. At the beginning of the simulation, R_h and P_b are within their normal ranges. Around

n=40, R_h rises to above the threshold while P_b stays normal. The supervisory controller makes a correction due to the high heart rate and waits for a reaction. During an actual ultrafiltration procedure, the supervisory controller would wait about 10 minutes before taking any other actions because of a high heart rate. For purposes of the simulation, the wait is shortened to about 30 seconds. The switch logic once again activates FSIA 30 seconds after the first correction since the patient's heart rate remains high. The supervisory controller waits 30 more seconds, and the switch logic rechecks R_h and P_b. This time, the heart rate is high and the blood pressure is low, so the switch logic activates FSIC. The fuzzy subsystem FISC decreases the ultrafiltration rate at about n=100, and shortly thereafter R_h and P_b begin to return to normal. Since the patient parameters return to normal before the supervisory controller checks if the reactivation of FSI is necessary, no further corrections are made.

Example 5

Figs. 11A, 11B and 11C show a simulation where the heart rate and blood pressure are both low and the user has specified a decrease of ultrafiltration when queried by the supervisory controller. The blood flow rate is set to 40 ml/min, and the replacement rates are both set to 100 ml/min. The minimum and maximum thresholds for the heart rate are chosen as 90 bpm and 105 bpm, and the minimum and maximum thresholds for the blood pressure are chosen as 70 mmHg and 95 mmHg. At the beginning of the simulation, R_h and P_b are within their normal ranges. At about n=80, R_h and P_b drop below their respective low thresholds, and FSIIB calculates an ultrafiltration rate decrease.

The switch logic forces FSII to wait 10 seconds (5 minutes for an actual ultrafiltration procedure) before another adjustment is made. Since the patient parameters never return to their respective normal ranges, the supervisory controller lowers the drain rate until the ultrafiltration rate is zero.

Example 6

Figs. 12A, 12B and 12C show a simulation where the patient parameters are both high and the user specifies an increase of the ultrafiltration rate. The blood flow rate is set to 40 ml/min, and the replacement rates are both set to 100 ml/min. The thresholds for the heart rate are chosen as 90 bpm and 105 bpm, and the thresholds for the blood pressure are chosen as 70 mmHg and 95 mmHg. At the beginning of the simulation, R_h and P_b are within their normal ranges. At about n=60, both the patient heart rate and blood pressure rise above their respective upper thresholds. After 20 seconds (30 minutes in an actual ultrafiltration procedure), the condition for activating FSII is met and the ultrafiltration rate is increased. Since the patient parameters never return to their respective normal ranges, the supervisory controller raises the drain rate until the ultrafiltration rate is 30% above the rate initially given. At this point, the hemofiltrator alerts the user that the maximum ultrafiltration rate has been set as the desired rate.

Example 7

Figs. 13A, 13B and 13C present a simulation where the patient is getting well enough to increase the ultrafiltration rate. The blood flow rate is set to 40 ml/min, and the replacement rates are both set to 100 ml/min. The

thresholds for the heart rate are chosen as 90 bpm and 105 bpm, and the thresholds for the blood pressure are chosen as 70 mmHg and 95 mmHg. At the beginning of the simulation, R_h and P_b are within their normal ranges. Once the heart rate and blood pressure are in the favorable regions, the supervisory controller waits 120 seconds (about 60 minutes in an actual ultrafiltration procedure) to detect transient behavior before increasing the drain pump flow rate. Since the heart rate and the blood pressure return to their normal ranges, no further adjustments are made.

Example 8

Figs. 14A, 14B and 14C depict a simulation where the supervisory controller adjusts the ultrafiltration due to a high filtered fraction. The patient parameters are both high for an extended period of time and the initial ultrafiltration rate of 132.6 ml/hr is increased to 172.4 ml/hr by increasing the drain rate from 332.6 ml/hr to 372.4 ml/hr. The latter flow rate would give a filtered fraction of 22.2% if the blood pumping were held at 40.0 ml/min. In order to bring the filtered fraction down to 20%, the blood pump flow rate must be increased to 44.3 ml/min.

The supervisory control system and the adaptive control system described above are not limited to use in a ultrafiltration procedure, but may find application in other medical systems that employ a pump for transferring a fluid, such as a heart-lung machine. Other suitable medical applications would be apparent to one of ordinary skill in the art.

It will be appreciated by persons skilled in the art that various modifications can be made to the systems and methods of the present invention without departing from the scope thereof which is defined by the appended claims.

What is claimed is:

1. A supervisory control system for a medical system having at least one pump for pumping fluid, said supervisory control system comprising:

a sensor for measuring the flow rate of fluid in a medical system generated by at least one pump, said flow rate sensor providing flow rate data signals correlated to the fluid flow rate;

at least one monitor for measuring at least one predetermined patient parameter, said least one patient parameter monitor providing patient parameter data signals correlated to said at least one patient parameter; and

a supervisory controller operably connected to said at least one pump in a medical system, to said flow rate sensor, and to said at least one patient parameter monitor, said controller receiving said flow rate data signals and said patient parameter data signals and analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule, said controller then providing an output signal to the at least one pump to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the at least one pump.

2. The supervisory control system of claim 1, wherein the sensor is selected from the group consisting of a flowmeter and a weight scale.

3. The supervisory control system of claim 1, wherein said at least one patient parameter monitor is selected from the group consisting of a blood pressure monitor providing blood pressure data signals, a heart rate monitor providing heart rate data signals, and combinations thereof.

4. The supervisory control system of claim 3, wherein the medical system is an ultrafiltration system and the at least one predetermined supervisory rule is selected from the group consisting of:

a) If heart rate is high and blood pressure is normal or low, then decrease ultrafiltration and wait a first predetermined time.

b) If blood pressure is low and heart rate is normal or high, then decrease ultrafiltration and wait a second predetermined time.

c) If blood pressure is low and heart rate is low, then provide the user a choice between a decrease or increase of the ultrafiltration rate and wait a third predetermined time.

d) If blood pressure is high and heart rate is high for a fourth predetermined time, then provide the user with a choice between a decrease or increase of the ultrafiltration rate.

e) If blood pressure is high and heart rate is low for a fifth predetermined time, then increase ultrafiltration.

f) The lowest possible value of ultrafiltration is a predetermined minimum rate per hour and the highest possible value of the ultrafiltration rate is a predetermined percentage above that of a predetermined maximum ultrafiltration rate.

g) If an increase in ultrafiltration occurs such that the filtered fraction is greater than a predetermined filtered fraction, increase the blood pump flow such that the filtered fraction equals the predetermined filtered fraction.

5. The supervisory control system of claim 1, further comprising a second sensor for measuring the flow rate of fluid in a medical system generated by a second pump, said second flow rate sensor providing second flow rate data signals correlated to the fluid flow rate, wherein said supervisory controller is further operably connected to said second pump and to said second flow rate sensor, said controller receiving said second flow rate data signals and analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule and said controller then providing an output signal to the second pump to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the second pump.

6. The supervisory control system of claim 5, further comprising a third sensor for measuring the flow rate of fluid in a medical system generated by a third pump, said second flow rate sensor providing third flow rate data signals

correlated to the fluid flow rate, wherein said supervisory controller is further operably connected to said third pump and to said third flow rate sensor, said controller receiving said third flow rate data signals and analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule and said controller then providing an output signal to the third pump to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the third pump.

7. The supervisory control system of claim 6, further comprising a fourth sensor for measuring the flow rate of fluid in a medical system generated by a fourth pump, said second flow rate sensor providing fourth flow rate data signals correlated to the fluid flow rate, wherein said supervisory controller is further operably connected to said fourth pump and to said fourth flow rate sensor, said controller receiving said fourth flow rate data signals and analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule and said controller then providing an output signal to the fourth pump to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the fourth pump.

8. An adaptive control system for controlling the pumping rate of at least one pump for pumping fluid in a medical system, said adaptive control system comprising:

a sensor for measuring the flow rate of fluid in a medical system generated by at least one pump, said flow rate sensor providing flow rate data signals correlated to the fluid flow rate; and

an adaptive controller operably connected to said at least one pump in a medical system and to said flow rate sensor, said controller receiving said flow rate data signals, using an adaptive law to generate a set of controller parameters for correcting time-dependent deviations of the flow rate from a predetermined flow rate, and using a control law to generate an output signal from the set of controller parameters for adjusting the pumping rate of fluid generated by the at least one pump to achieve the predetermined flow rate, said controller then providing the output signal to the at least one pump on a periodic ongoing basis.

9. The adaptive control system of claim 8, wherein the sensor is a flowmeter.

10. The adaptive controller system of claim 8, wherein the sensor is a weight scale providing weight data signals and said flow rate data signals comprise the rate change in the weight data signals.

11. The adaptive control system of claim 8, wherein said adaptive law further includes parameter projections to limit said output signal to a range between a predetermined minimum output signal and a predetermined maximum output signal.

12. Continuous hemofiltration system for removal of fluid from the blood of a patient, comprising:

a hemofilter;

a first pump for pumping blood from a patient through said hemofilter and back to the patient;

a flowmeter downstream of said first pump to measure the blood outflow from the blood pump, said flowmeter generating blood flow rate data signals correlated to the blood flow rate;

a first reservoir for maintaining a supply of infusate;

a second pump for pumping the infusate from said first reservoir to said hemofilter;

a second reservoir for receiving drained fluid from said hemofilter;

a third pump for pumping the drained fluid from said hemofilter to said second reservoir; and

an adaptive controller operably connected to said first pump and to said blood flowmeter, said adaptive controller receiving said blood flow rate data signals, using an adaptive law to generate a set of controller parameters for correcting time-dependent deviations of the flow rate of the respective fluid from a predetermined blood flow rate, and using a control law to generate an output signal from the set of controller parameters for adjusting the pumping rate of fluid generated by the first pump to achieve the predetermined blood flow rate, said adaptive controller then providing the output signal to the first pump on a periodic ongoing basis.

13. The continuous hemofiltration system of claim 12, further comprising:

at least one monitor for measuring at least one predetermined patient parameter, said least one patient parameter monitor providing patient parameter data signals correlated to said at least one patient parameter;

a first scale to measure the weight of infusate in said first reservoir, said first scale generating infusate flow rate data signals correlated to the infusate weight;

a second scale to measure the weight of drained fluid in said second reservoir, said second scale generating drained fluid flow rate data signals correlated to the drained fluid weight; and

a supervisory controller operably connected to said pumps, to said flowmeter, to said scales, and to said at least one patient parameter monitor, said controller receiving said flow rate data signals and said patient parameter data signals and analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule, said controller then providing an output signal to said pumps to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by each at least one pump.

14. Continuous hemofiltration system for removal of fluid from the blood of a patient, comprising:

a hemofilter;

a first pump for pumping blood from a patient through said hemofilter and back to the patient;

a flowmeter downstream of said first pump to measure the blood outflow from the blood pump, said flowmeter generating blood flow rate data signals correlated to the blood flow rate;

a first reservoir for maintaining a supply of infusate;

a first scale to measure the weight of infusate in said first reservoir, said first scale generating infusate flow rate data signals correlated to the infusate weight;

a second pump for pumping the infusate from said first reservoir to said hemofilter;

a second reservoir for receiving drained fluid from said hemofilter;

a second scale to measure the weight of drained fluid in said second reservoir, said second scale generating drained fluid flow rate data signals correlated to the drained fluid weight;

a third pump for pumping the drained fluid from said hemofilter to said second reservoir;

at least one monitor for measuring at least one patient parameter, said least one patient parameter monitor providing patient parameter data signals correlated to said at least one patient parameter; and

a supervisory controller operably connected to said pumps, to said flowmeter, to said scales, and to said at least one patient parameter monitor, said controller receiving the blood flow rate data signals, the infusate flow rate data signals, the drained fluid flow rate data signals, and the patient parameter data signals, said supervisory controller analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule, and said supervisory controller then providing an output signal to one or more of said pumps to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the one or more of said pumps.

15. The continuous hemofiltration system of claim 14, further comprising an adaptive controller operably connected to said first pump and to said blood flowmeter, said adaptive controller receiving said blood flow rate data signals, using an adaptive law to generate a set of controller parameters for correcting time-dependent deviations of the flow rate of the respective fluid from a predetermined blood flow rate, and using a control law to generate an output signal from the set of controller parameters for adjusting the pumping rate of fluid generated by the first pump to achieve the predetermined blood flow rate, said adaptive controller then providing the output signal to the first pump on a periodic ongoing basis.

16. Continuous hemofiltration system for removal of fluid from the blood of a patient, comprising:

a hemofilter;

a first pump for pumping blood from a patient through said hemofilter and back to the patient;

a flowmeter downstream of said first pump to measure the blood outflow from the blood pump, said flowmeter generating blood flow rate data signals correlated to the fluid flow rate;

a first reservoir for maintaining a supply of infusate;

a first scale to measure the weight of infusate in said first reservoir, said first scale generating infusate flow rate data signals correlated to the infusate weight;

a second pump for pumping the infusate from said first reservoir to said hemofilter;

a second reservoir for receiving drained fluid from said hemofilter;

a second scale to measure the weight of drained fluid in said second reservoir, said second scale generating drained fluid flow rate data signals correlated to the drained fluid weight;

a third pump for pumping the drained fluid from said hemofilter to said second reservoir;

at least one monitor for measuring at least one patient parameter, said least one patient's parameter monitor providing patient parameter data signals correlated to said at least one patient parameter;

a supervisory controller operably connected to said pumps, to said flowmeter, to said scales, and to said at least one patient parameter monitor, said controller receiving the blood flow rate data signals, the infusate flow rate data signals, the drained fluid flow rate data signals, and the patient parameter data signals, said supervisory controller analyzing said signals utilizing fuzzy logic based on at least one predetermined supervisory rule, and said supervisory controller then providing an output signal to one or more of said pumps to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the one or more of said pumps; and

an adaptive controller operably connected to said first pump and to said blood flowmeter, said adaptive controller receiving said blood flow rate data signals, using an adaptive law to generate a set of controller parameters for correcting time-dependent deviations of the flow rate of the respective fluid from a predetermined blood flow rate, and using a control law to generate an output signal from the set of controller parameters for adjusting the pumping rate of fluid generated by the first pump to achieve the predetermined blood flow rate, said adaptive controller then providing the output signal to the first pump on a periodic ongoing basis.

17. Hemofiltration method for removal of fluid from the blood of a patient, comprising:

pumping blood from a patient through a hemofilter and back to the patient;

monitoring the blood outflow from the blood pump and generating blood flow rate data signals;

maintaining a supply of infusate in a first reservoir;

monitoring the weight of infusate in said first reservoir and generating infusate flow rate data signals;

pumping the infusate to the hemofilter;

pumping drained fluid from the hemofilter into a second reservoir;

monitoring the weight of drained fluid in said second reservoir and generating drained fluid flow rate data signals;

monitoring at least one predetermined patient parameter, such as patient heart rate and/or blood pressure, and generating parameter data signals correlated thereto; and

controlling the pumping rate of the blood, the drained fluid, and the infusate with a programmed computer, said computer being responsive to the flow rate data signals and to said parameter data signals,

said computer

receiving said rate data and said parameter data signals;

utilizing a supervisory controller to analyze said signals utilizing fuzzy logic based on at least one predetermined supervisory rule; and

generating an output signal to each said pump to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by each pump.

18. Hemofiltration method for removal of fluid from the blood of a patient, comprising:

pumping blood from a patient through a hemofilter and back to the patient;

sensing the performance of the blood pump and generating a first set of controller parameters from a first adaptive law;

monitoring the blood outflow from the blood pump and generating blood flow rate data signals;

maintaining a supply of infusate in a first reservoir;

monitoring the weight of infusate in said first reservoir and generating infusate flow rate data signals;

pumping the infusate to the hemofilter;

sensing the performance of the infusate pump and generating a second set of controller parameters from a second adaptive law;

pumping drained fluid from the hemofilter into a second reservoir;

monitoring the weight of drained fluid in said second reservoir and generating drained fluid flow rate data signals;

sensing the performance of the drained fluid pump and generating a third set of controller parameters from a third adaptive law; and

controlling the pumping rate of the blood, the drained fluid, and the infusate with a programmed computer to correspond to a set of predetermined pumping rates, said computer being responsive to the flow rate data signals and the controller parameters,

said computer

receiving said flow rate data signals and the controller parameters;

using a control law to generate an output signal from the flow rate data signals and the controller parameters for correcting time-dependent deviations of the flow rate from the set of predetermined pumping rates, and

providing the output signal to the at least one pump on a periodic ongoing basis.

19. A method of controlling a pump pumping fluid in a medical system comprising the steps of:

measuring the flow rate of a fluid in a medical system generated by a pump to obtain flow rate data signals correlated to the fluid flow rate;

measuring at least one patient parameter to obtain patient parameter data signals correlated to said at least one patient parameter; and

analyzing said flow rate data signals and said patient parameter data signals utilizing fuzzy logic based on at least one predetermined supervisory rule; and

providing an output signal to the pump to adjust, as necessary on a periodic ongoing basis, the flow rate of fluid generated by the pump.

20. A method of controlling a pump pumping fluid in a medical system comprising the steps of:

measuring the flow rate of a fluid in a medical system generated by a pump to obtain flow rate data signals correlated to the fluid flow rate;

generating a set of controller parameters from said flow rate signals for correcting time-dependent deviations of the flow rate from a predetermined flow rate;

generating an output signal using a control law from the set of controller parameters, for adjusting the pumping rate of fluid generated by the pump to achieve the predetermined flow rate; and

providing the output signal to the pump on a periodic ongoing basis to correct the time-dependent deviations of the flow rate from the predetermined flow rate.